



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-002

April 22, 2013

Barco (Healthcare Division)  
c/o: Lieven De Wandel  
Regulatory Affairs Officer  
35 President Kennedypark  
8500 Kortrijk  
Belgium, 8500

Re: K122167  
Trade Name: Nexxis OR  
Regulation Number: 21 CFR 870.2450  
Regulation Name: Medical cathode-ray tube display  
Regulatory Class: Class II  
Product Code: DXJ  
Dated: April 5, 2013  
Received: April 8, 2013

Dear Lieven De Wandel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Owen P. Faris -S**

for Bram D. Zuckerman, M.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

k122167

## Indications for Use

510(k) Number (if known):

Device Name:

Indications For Use:

*The Barco Nexxis OR system is designed to allow transfer, selection and distribution of A/V signals and medical images from various commercially available instruments that are commonly used in a medical procedure laboratory or operating room.*

*The Barco Nexxis OR system is also designed for transfer, selection and distribution of human interface signals and control signals of non-medical room equipment.*

*The Barco Nexxis OR system allows control and selection of these signals from a central point.*

*The Barco Nexxis OR system is not intended to be used for remote or robotically-assisted surgery.*

*The Barco Nexxis OR system is not intended to be used in the vicinity of MRI or other devices that use strong magnetic fields.*

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

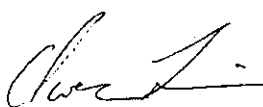
Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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Concurrence of CDRH; Office of Device Evaluation (ODE)



Owen P. Faris -S

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